

### REMARKS

Claims 3, 4, 7, 9-12, 15, 17-20, and 23-39 are pending in this application. Claims 1, 2, 5, 6, 8, 13, 14, 16, 21, and 22 are canceled. Applicants note that Examiner has not taken into consideration the preliminary amendment to the claims filed on December 3, 2004. Applicants request entry of the preliminary amendment. All amendments herein are made in relation to the claims presented in the preliminary amendment.

#### Priority Claim

Without acquiescence to the Office Action's determination of the priority date, Applicants will submit a certified English translation of the priority document in due course to show the priority date to which the claims are entitled.

#### Objections

The years of deposits indicated on page 16 of the specification were objected to for not being translated into Gregorian calendar. Appropriate corrections have been made.

Claims 9, 11, 12, 15, and 17 stand objected to for using the term "base" instead of "nucleotide." Appropriate corrections have been made.

#### Certification Under 37 C.F.R. § 1.808

The undersigned hereby states that the transformants identified in the specification as pUCNTkmTn5-KNK-L/HB101 and pUCNT-Tn5-MuKNK-L1/HB101 were deposited at the International Patent Organism Depository in Japan pursuant to the Budapest Treaty and that the deposited microorganisms will be available to the public according to 37 C.F.R. § 1.808.

#### Rejections Under § 101

Claims 3, 4, 7, 9-12, 15, 17-20, 23-30, and 34 stand rejected under § 101 for being directed to non-statutory subject matter. Claims 3, 4, 7, 9, 11, 12, 15, 17-20, 23-27, and 34 are amended to specify that the genes, polynucleotides, proteins, or enzymes are "isolated and purified," as suggested by Examiner. Claim 10 is amended to recite a strain of

*Stenotrophomonas* that is not a product of nature. Claims 28-30 are amended to specify that the transformation occurs in a host cell, thus excluding human beings.

Applicants submit that claims 3, 4, 7, 9-12, 15, 17-20, 23-30, and 34 are directed to statutory subject matter and request withdrawal of the rejections under § 101.

#### Rejections Under § 112

Claims 4, 7, 12, 15, 18-20, and 23-38 stand rejected under § 112, second paragraph, for indefiniteness. Claims 3, 9-11, 15, 18-20, and 23-38 stand rejected under § 112, first paragraph, for lack of written description and/or non-enablement. Applicants traverse these rejections.

Claim 3: The rejections under § 112, first paragraph, for lack of written description and non-enablement are overcome by amendment specifying a requisite degree of homology, instead of “substantially identical,” with SEQ ID NO: 2. Support for this amendment can be found in the specification at page 11, lns. 9-15.

Applicants contend that claim 3 recites sufficient structural characteristics of the claimed gene in compliance with the written description requirement. Applicants also contend that claim 3 is sufficiently enabled by the disclosure. Example 10 (p. 32) provides a detailed description of how a random-mutated acylase enzyme recombinant library can be produced. Example 11 (p. 32, 33) provides a detailed description of how random-mutant strains can be screened. Example 11 also discloses one such mutant having a Met204 → Val substitution. With the specific guidance provided in Examples 10 and 11, one of ordinary skill in the art could produce other mutant enzymes having the requisite degree of homology without undue experimentation.

Claim 4: The rejection under § 112, second paragraph, for indefiniteness is overcome by amendment reciting SEQ ID NO: 2 as the amino acid sequence.

Claim 7: The rejection under § 112, second paragraph, for indefiniteness is overcome by amendment reciting SEQ ID NO: 2 as the amino acid sequence. The rejection under § 112, first paragraph, for lack of written description and non-enablement is overcome by amendment reciting the target (signal sequence), location (N-terminus), and manner (enzymatic deletion) of

the post-translational modification. Support for these amendments can be found in the specification at page 12, lns. 10-17.

Applicants contend that claim 7 sufficiently characterizes the nature of the post-translational modification in compliance with the written description requirement. Applicants also contend that claim 7 is sufficiently enabled by the disclosure. Claim 7 recites enzymatic deletion of the signal sequence at the N-terminus of SEQ ID NO: 2. With the complete identification of SEQ ID NO: 2 provided in the specification, one of skill in the art could easily identify the signal sequence using any analytic method known at the time, including readily available protein sequence analysis software.

Claim 9: The rejections under § 112 are overcome according to the same rationale presented for claim 3, from which claim 9 depends.

Claim 10: The rejections under § 112, first paragraph, for lack of written description and non-enablement are overcome by amendment reciting the specific strain of *Stenotrophomonas* disclosed in the specification.

Claim 11: As in claim 3, the rejection under § 112, first paragraph, for lack of written description is overcome by amendment specifying a requisite degree of homology, instead of “substantially identical,” with SEQ ID NO: 2. Applicants contend that claim 11 is in compliance with the written description requirement under the same rationale presented for claim 3.

Claim 12: The rejection under § 112, second paragraph, for indefiniteness is overcome by amendment reciting SEQ ID NO: 2 as the amino acid sequence.

Claim 15: As in claim 7, the rejection under § 112, second paragraph, for indefiniteness is overcome by amendment reciting SEQ ID NO: 2 as the amino acid sequence. Also as in claim 7, the rejections under § 112, first paragraph, for lack of written description and non-enablement are overcome by amendment reciting the target (signal sequence), location (N-terminus), and manner (enzymatic deletion) of the post-translational modification. Applicants contend that claim 15 is in compliance with the written description requirement and is sufficiently enabled under the same rationale presented for claim 7.

Claim 18: The rejections under § 112, first paragraph, are overcome according to the same rationale presented for claim 11, from which claim 18 depends. The rejection under § 112, second paragraph, for dependency on rejected claim 11 is overcome by amendment to claim 11 as explained above.

Claim 19: Under the same rationale presented for claim 3, the rejections under § 112, first paragraph, for lack of written description and non-enablement are overcome by amendment specifying a requisite degree of homology, instead of “substantially identical,” with SEQ ID NO: 2 and a requirement for  $\beta$ -lactam acylase activity in the mutants. The basis for the rejection under § 112, second paragraph, is unclear and clarification or withdrawal of this rejection is requested.

Claim 20: The rejection under § 112, second paragraph, for indefiniteness is overcome by amendment reciting SEQ ID NO: 2 as the amino acid sequence.

Claim 23: As in claim 7, the rejection under § 112, second paragraph, for indefiniteness is overcome by amendment reciting SEQ ID NO: 2 as the amino acid sequence. Also as in claim 7, the rejections under § 112, first paragraph, for lack of written description and non-enablement are overcome by amendment reciting the target (signal sequence), location (N-terminus), and manner (enzymatic deletion) of the post-translational modification. Applicants contend that claim 23 is in compliance with the written description requirement and is sufficiently enabled under the same rationale presented for claim 7.

Claim 24: The rejection under § 112, second paragraph, for indefiniteness as depending on rejected claim 3 is overcome by amendment to claim 3, as explained above. The rejections under § 112, first paragraph, for lack of written description and non-enablement are overcome by amendment reciting the structure of the translation regulatory sequence, as disclosed in the specification at p. 14, lns. 30-35 and p. 15, lns. 1-3. Applicants contend that sufficient structural identity is recited in claim 24 to comply with the written description requirement and to enable one of ordinary skill in the art to make the claimed gene.

Claim 25: As in claim 24 and under the same rationale, the rejections under § 112 are overcome by amendment to claim 3 and recitation of the structure of the translation regulatory

sequence.

Claim 26: The rejection under § 112, second paragraph, for indefiniteness is overcome by amendment clarifying the source of the regulatory sequences.

Claim 27: The rejection under § 112, second paragraph, for having an improper multiple claim dependency is overcome by prior amendment made in the preliminary amendment of December 3, 2004. Claim 27 is directed to a recombinant vector comprising one or more copies of the gene according to claim 3. The rejections under § 112, first paragraph, for lack of written description and non-enablement are overcome by amendment to claim 3, from which claim 27 depends.

Claim 28: The rejection under § 112, second paragraph, for having an improper multiple claim dependency is overcome by prior amendment made in the preliminary amendment of December 3, 2004. The rejections under § 112, first paragraph, for lack of written description and non-enablement are overcome by amendment to claim 3, from which claim 28 indirectly depends. In addition, the rejection under § 112, first paragraph, for non-enablement of other host organisms is overcome by amendment reciting a cell as the host organism.

Claims 29 and 30: As in claim 28 and under the same rationale, the rejections under § 112 are overcome by prior amendment removing multiple dependency, amendment to claim 3, and recitation of a cell as the host organism.

Claims 31 and 32: The rejection under § 112, second paragraph, for having an improper multiple claim dependency is overcome by prior amendment made in the preliminary amendment of December 3, 2004. The rejection under § 112, first paragraph, for non-enablement because of failure to indicate public availability of the deposited materials is overcome by the statement regarding public availability provided above.

Claim 33: The rejection under § 112, second paragraph, for having an improper multiple claim dependency is overcome by prior amendment made in the preliminary amendment of December 3, 2004. As in claim 28 and under the same rationale, the rejections under § 112, first paragraph, for lack of written description and non-enablement are overcome by amendment to

claim 3, from which claim 33 indirectly depends.

Claim 34: The rejection under § 112, second paragraph, for having an improper multiple claim dependency is overcome by prior amendment made in the preliminary amendment of December 3, 2004. The rejections under § 112, first paragraph, for lack of written description and non-enablement are overcome by amendment to claim 11, from which claim 34 depends.

Claim 35: The rejection under § 112, second paragraph, for having an improper multiple claim dependency is overcome by prior amendment made in the preliminary amendment of December 3, 2004. The rejection under § 112, first paragraph, for lack of written description and non-enablement is overcome by amendment deleting the allegedly unsupported subject matter.

Claim 36: The rejection under § 112, second paragraph, for having an improper multiple claim dependency is overcome by prior amendment made in the preliminary amendment of December 3, 2004. The rejections under § 112, first paragraph, for lack of written description and non-enablement are overcome by amendment to claim 3, from which claim 36 indirectly depends.

Claims 37 and 38: The rejection under § 112, second paragraph, for having an improper multiple claim dependency is overcome by prior amendment made in the preliminary amendment of December 3, 2004. The rejections under § 112, first paragraph, for lack of written description and non-enablement are overcome by amendment to claim 11, from which claims 37 and 38 indirectly depend.

Claim 39: This claim was newly presented in the preliminary amendment of December 3, 2004, but was not rejected in the Office Action. However, amendment is made to further clarify the subject matter.

Rejections Under § 102

Claims 26, 27, 29, and 34 stand rejected under § 102(b) as being anticipated by U.S. Patent No. 5,168,048 (*Quax*). These claims depend directly or indirectly from claim 3, which is amended to more clearly define the subject matter as explained above. Also, claims 26, 29, and 34 are amended to further define the subject matter as explained above.

Claim 26 recites a gene and claim 34 recites a polynucleotide encoding for a protein comprising an amino acid sequence identical to or having not less than 90% homology with SEQ ID NO: 2, which contains 636 amino acids. Claim 27 recites a vector containing the gene according to claim 3 and claim 29 recites a transformant created with the vector in a gram-negative microorganism.

*Quax* describes a gene encoding for penicillin G acylase having the amino acid sequence identified in SEQ ID NO: 1 (cols. 10-16). SEQ ID NO: 1 of *Quax* contains a sequence of 817 amino acids. In terms of sequence length, SEQ ID NO: 1 of *Quax* is about 28% larger than SEQ ID NO: 2 of the present invention. The gene described in *Quax* does not encode for a protein comprising an amino acid sequence of SEQ ID NO: 2 or having not less than 90% homology with SEQ ID NO: 2, as recited in claims 26, 27, 29, and 34. For at least this reason, Applicants submit that claims 26, 27, 29, and 34 are not anticipated by *Quax* and respectfully request withdrawal of this rejection.

For the same reasons, Applicants submit that unexamined claim 39, reciting a transformant created by a recombinant vector containing the gene of claim 3, is not anticipated by *Quax*.

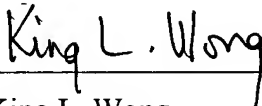
CONCLUSION

Applicants respectfully submit that the present application is now in condition for allowance. The Examiner is invited to contact Applicants' representative to discuss any issue that would expedite allowance of this application.

No extensions of time or other fees are required in connection with the filing of this response. However, in case the filing of this paper is deemed not timely, Applicants petition for an appropriate extension of time. The Commissioner is authorized to charge all required fees, fees under § 1.17, or all required extension of time fees, or to credit any overpayment to Deposit Account No. 11-0600 (Kenyon & Kenyon LLP).

Respectfully submitted,

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King L. Wong  
Reg. No. 37,500

KENYON & KENYON LLP  
1500 K Street, N.W.  
Washington, DC 20005  
Tel: (202) 420-4200  
Fax: (202) 420-4201